

SUBCHAPTER E—COMMODITY LABORATORY TESTING PROGRAMS

PART 90—INTRODUCTION

Subpart A—Scope of Subchapter

Sec.

90.1 General.

Subpart B—Subchapter Definitions

90.2 General terms defined.

Subpart C—Good Laboratory Practices for Commodity Laboratory Analyses

90.3 General.

90.4–90.100 [Reserved]

Subpart D—Quality Assurance

90.101 General.

90.102 Quality assurance review.

90.103 Maintenance of quality control records.

90.104–90.200 [Reserved]

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Subpart A—Scope of Subchapter

§ 90.1 General.

This subchapter sets forth the functions and responsibilities of the Science and Technology (S&T) of the Agricultural Marketing Service (AMS) relating to:

(a) The performance of comprehensive analytical tests and laboratory determinations of agricultural commodities and processed products.

(b) The conduct of experiments and collaborative studies to validate new analytical procedures and improved methodologies in order to promote faster, more precise, or safer laboratory testing for agricultural commodities and processed products.

(c) The supervised issuance of external quality control or proficiency check samples to laboratories under the Science and Technology's direction or performance review in order to regularly spot check and assess that analytical or test data produced by each laboratory is reproducible, precise, and reliable for a specific test program.

(d) The granting of laboratory program accreditation or certification or approval for specialty testing of agricultural commodities and products.

(e) The licensing of chemists to analyze cottonseed in order to certify its quality and grade.

(f) The granting of certification to non-federal laboratories for testing for trichinae in horsemeat for export to the European Community (EC).

(g) The granting of acceptance of standardized methodology or new procedures for commodity testing.

(h) The auditing of the facilities, equipment, quality control procedures, standard methodologies, and good laboratory practices for a commodity testing program of a laboratory.

(i) The examination of plants for novelty and distinctiveness in order to grant certificates of protection for new varieties of sexually reproduced plants, and the provision of other fee based services authorized by the Plant Variety Protection Act.

(j) The extension or coordination of research for the determination of a new chemical analyte or microorganism in a commodity product or food.

(k) The analysis of imported flue-cured and burley tobacco for pesticide residues.

(l) The supervision and implementation of the State enforcement of the recordkeeping requirements for private applicators of restricted-use pesticides for agricultural production.

[58 FR 42414, Aug. 9, 1993, as amended at 61 FR 51350, Oct. 2, 1996; 65 FR 64309, Oct. 26, 2000]

Subpart B—Subchapter Definitions

§ 90.2 General terms defined.

Words used in the regulations in this subchapter in the singular form will import the plural, and vice versa, as the case may demand. As used throughout the regulations in this subchapter and unless the context requires otherwise, the following terms will be construed to mean:

Agricultural Marketing Service, USDA

§ 90.102

Act. The Agricultural Marketing Act of 1946 (Title II of the act of Congress approved August 14, 1946, 60 Stat. 1087–1091, as amended; 7 U.S.C. 1621–1627).

Administrator. The Administrator of the Agricultural Marketing Service, or any officer or employee of the Service, to whom authority has been delegated, or to whom authority may be delegated, to act in his or her stead.

Cooperative agreement. An agreement between the Agricultural Marketing Service and another Federal agency or a State agency, or other agency, organization or person that defines in the general terms the basis on which the parties concerned will cooperate to serve a mutual interest on an agricultural service project. The responsibilities for AMS and each cooperator are stated in the document along with the conditions as applicable.

Department. The United States Department of Agriculture.

Deputy Administrator. The Deputy Administrator of the Science and Technology program of the Agricultural Marketing Service agency, or any officer or employee of this agency to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act.

Laboratories. Science and Technology laboratories performing the official analyses described in this subchapter.

Program. The Science and Technology (S&T) program of the Agricultural Marketing Service (AMS) which performs official analytical testing services, issues licenses for cottonseed chemists, and conducts quality assurance reviews and grants accreditation or certification for commodity testing programs of laboratories.

Quality assurance. The assurance that there is accuracy of analytical data using proficiency check sample or analyte recovery techniques. In addition, the certainty that there is strict adherence by the analysts in following the quality control details in the recommended or official methods for reagents, laboratory apparatus and procedures. The overall objective of quality assurance, as a comprehensive program, is to ensure that all analytical data produced by the laboratory meets certain quality criteria and that all

data produced is reproducible, precise, and accurate.

Quality control. The system of close examination of the critical details of an analytical procedure in order to have the proper equipment parameters, techniques, supplies and reagents to achieve a predetermined level of quality data, with the performance of a particular laboratory analysis.

Secretary. The Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his or her stead.

Service. The Agricultural Marketing Service of the United States Department of Agriculture.

[58 FR 42414, Aug. 9, 1993, as amended at 61 FR 51350, Oct. 2, 1996; 65 FR 64309, Oct. 26, 2000]

Subpart C—Good Laboratory Practices for Commodity Laboratory Analyses

§ 90.3 General.

Laboratory service programs of laboratories certified and approved by the Science and Technology shall have good laboratory practice (GLP) requirements that are generalized in this subpart.

[58 FR 42414, Aug. 9, 1993, as amended at 61 FR 51350, Oct. 2, 1996; 65 FR 64309, Oct. 26, 2000]

§§ 90.4–90.100 [Reserved]

Subpart D—Quality Assurance

§ 90.101 General.

Laboratory service programs of laboratories certified and approved by the Science and Technology shall have quality assurance requirements that are generalized in this subpart.

[58 FR 42414, Aug. 9, 1993, as amended at 61 FR 51350, Oct. 2, 1996; 65 FR 64309, Oct. 26, 2000]

§ 90.102 Quality assurance review.

(a) Each laboratory performing tests and analysis under this subchapter will be subject to a quality assurance program evaluation at least annually, and

§ 90.103

more often if deemed necessary by the Deputy Administrator. Such evaluation will include:

(1) A review of the adequacy of quality control measures taken by the laboratory for the standardized method of analysis for a commodity and its related products;

(2) A review of the laboratory methodologies and procedures;

(3) A review of records for the calibration and maintenance of equipment;

(4) A review of records documenting sample handling;

(5) The evidence of quality control records;

(6) The evidence of correct reporting and determination of analytical data.

(b) A laboratory will receive a quality assurance report following the review. This evaluation will address any necessary improvements to the laboratory program(s) being examined.

[58 FR 42414, Aug. 9, 1993, as amended at 65 FR 64309, Oct. 26, 2000]

§ 90.103 Maintenance of quality control records.

Quality control records pertaining, but not limited to the following areas, shall be retained by the laboratory for at least the 3 most recent years:

(a) Prepared solution standardizations;

(b) Recovery studies by known analyte additions;

(c) The purity checks of reagents and test materials;

(d) Apparatus and equipment calibrations;

(e) The quality examination and testing of materials;

(f) The mandatory participation in proficiency check sample testing or collaborative studies;

(g) Daily critical parameter checks of equipment, such as temperature readings;

(h) The equivalency tests of new procedures with standard methodologies.

7 CFR Ch. I (1–1–16 Edition)

§§ 90.104–90.200 [Reserved]

PART 91—SERVICES AND GENERAL INFORMATION

Subpart A—Administration

Sec.

91.1 General.

91.2 Definitions.

91.3 Authority.

Subpart B—General Services

91.4 Kinds of services.

91.5 Where services are offered.

91.6 Availability of services.

Subpart C—Application for Services

91.7 Nondiscrimination.

91.8 Who may apply.

91.9 How to make an application.

91.10 Information required in connection with an application.

91.11 Filing of an application.

91.12 Record of filing time and laboratory tests.

91.13 When an application may be rejected.

91.14 When an application may be withdrawn.

Subpart D—Laboratory Service

91.15 Basis of a laboratory service.

91.16 Order of a laboratory service.

91.17 Postponing a laboratory service.

91.18 Financial interest of a scientist.

Subpart E—Samples

91.19 General requirements of suitable samples.

91.20 Shipping.

91.21 Protecting samples.

91.22 Disposition of analyzed sample.

Subpart F—Method Manuals

91.23 Analytical methods.

Subpart G—Reporting

91.24 Reports of test results.

91.25 Certificate requirements.

91.26 Issuance of certificates.

91.27 Corrections to certificates prior to issuance.

91.28 Issuance of corrected certificates or amendments for analysis reports.

91.29 Issuance of duplicate certificates or reissuance of an analysis report.

91.30 Maintenance and retention of copies of certificates or analysis reports.